UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PETER NASH,
JOHN W. ROSEVEAR, deceased, by
DONALD L. ROBINSON, his legal representative, and
DONALD L. ROBINSON

Appeal 2006-3378
Application 09/616,843[1]
Technology Center 1600

ON BRIEF

Before ADAMS, GRIMES, and LINCK, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods of decreasing the waste of dietary protein in food animals. The examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] This application is related to Serial No. 10/025,567, which is pending before us as Appeal No. 2006-2575.

BACKGROUND

The bacteria *Peptostreptococcus anaerobius*, *Clostridium aminophilum*, and *Clostridium sticklandii* are among organisms "responsible for wasting up to 25 percent of the protein in cattle diets. This is a loss of as much as $25 billion annually to cattle producers . . . ." (Specification 2.)

The Specification discloses that these organisms act by degrading protein consumed by the host to ammonia. (*Id.*) The ammonia is then "converted to urea by the liver and kidneys and thus lost to the host when excreted as urine. These deleterious organisms also compete with beneficial organisms which the host needs for the efficient utilization of ammonia." (*Id.*)

Antibodies to these bacteria can be produced by inoculating female birds with a bacterial immunogen, and then harvesting the eggs from the inoculated birds. (*Id.* at 6.) "The total antibody-containing contents of the eggs are [then] separated from the shells," dried, and mixed with animal feed. (*Id.* at 6-7.)

The Specification discloses that orally administering the dried antibody-containing egg preparations will inhibit the "ability of colony-forming protein-wasting organisms, such as *P. anaerobius*, *C. sticklandii* and *C. aminophilum* . . . to adhere in the rumen or intestinal tracts of food animals and thus reduce their ability to multiply, grow and colonize." (*Id.* at 8 (underlining omitted).)

DISCUSSION

1. CLAIMS

Claims 14-16, 19-24, and 27-32 are pending and on appeal. (Answer 2.)

Claim 14 is representative and reads as follows:

> 14. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P. anaerobius*, said method comprising:
> A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P. anaerobius*;
> B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
> C. Harvesting the eggs laid by the birds;
> D. Separating the entire contents of said harvested eggs from the eggshells;
> E. Drying said separated entire contents of said harvested eggs;
> F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water to provide antibody-containing animal feed or water; and
> G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens, to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

Thus, claim 14 is directed to a process of promoting the growth of food animals by inhibiting the waste of protein within the animals' digestive tract. The claim recites the steps of making an antibody-containing dried egg

composition, distributing the composition in animal feed or water, and then supplying the feed or water to the animal. The antibody-containing composition is made by inoculating female birds with P antigen from *P. anaerobius*, allowing the birds to produce IgY, IgM, and IgA antibodies to the antigen, harvesting the birds' eggs, separating the entire contents of the eggs from the shells, and drying the contents of the eggs.

We interpret claim 14 to require inoculation with isolated P antigen, as opposed to whole *P. anaerobius* cells. This interpretation is supported by the language of claim 14 itself, which requires inoculating with "P antigen from *P. anaerobius*," i.e., P antigen derived from *P. anaerobius* cells.

This claim interpretation is also supported by the prosecution history. Originally filed claim 10 recited inoculating with "the particular targeted protein-wasting immunogen." The Examiner rejected this claim language as indefinite, reasoning that the claim language did not adequately define the "immunogen/antigen that w[as] used to inoculate the bird." Office action mailed Feb. 9, 2001, pp. 3-4.

In response to that Office action, Appellants introduced claim 14, among others. Appellants argued that "Claim 14 defines applicants' method of promoting animal growth caused by a protein wasting immunogen. The immunogen is P antigen from P. anaerobius. [Specification,] Example 17, page 23, lines 15-20." Response filed May 11, 2001, page 6. The example that Appellants pointed to describes inoculation of chickens with isolated P antigen. Thus, Appellants' description of the claimed method is consistent with our interpretation that claim 14 requires inoculating with isolated P antigen.

The Specification discloses that P antigen can be prepared by culturing *P. anaerobius* in broth, recovering the culture by low speed centrifugation, removing whole cells by centrifugation, and recovering the P antigen as the supernatant from the separated whole cells. (Specification 17.)

Claims 15 and 16 recite essentially the same processes as claim 14. However, instead of P antigen from *P. anaerobius*, claims 15 and 16 recite that the birds are immunized with CS antigen from *Clostridium sticklandii* and CA antigen from *Clostridium aminophilum*, respectively. As with claim 14, we interpret claims 15 and 16 to be limited to methods comprising inoculating with isolated CS and CA antigen, respectively.

The Specification discloses that these antigens can be prepared by culturing *C. sticklandii* or *C. aminophilum* in broth, recovering the culture by low speed centrifugation, removing whole cells by centrifugation, and recovering the CS or CA antigen as the supernatant from the separated whole cells. (Specification 17-18.) Thus, the pending claims all require obtaining an antibody-containing dried egg composition by inoculating birds with an isolated bacterial antigen that can be separated from whole cells in culture by centrifugation.

2. OBVIOUSNESS OF CLAIMS 14-16

Claims 14-16 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Tokoro,[2] Krause,[3] Coleman,[4] and Pimentel.[5]

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[2] Tokoro, U.S. Patent, 5,080,895, issued January 14, 1992.
[3] Krause et al., "An rRNA Approach for Assessing the Role of Obligate Amino Acid-Fermenting Bacteria in Ruminal Amino Acid Deamination," *Applied and Environmental Microbiology*, Vol. 62, No. 3, pp. 815-821 (1996).

The Examiner cites Tokoro as disclosing a method having the steps of inoculating egg laying hens with immunogens such as *E. coli*, harvesting the antibody-containing non-shell components of the egg, drying the non-shell components of the egg to form a powder, and adding the dried powder to animal feed. (Answer 5.) The Examiner notes that Tokoro discloses that "the method of making bird antibody to any bacteria of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive." (*Id.*)

The Examiner further notes that Tokoro does not disclose inoculating hens with P antigen, CS antigen, or CA antigen. (*Id.* at 5-6.) To meet this deficiency, the Examiner cites Krause as disclosing that, by converting amino acids in the rumen to ammonia, *P. anaerobius*, *C. aminophilum*, and *C. sticklandii* waste significant amounts of feed protein in livestock, thereby reducing the animals' growth. (*Id.* at 6.) The Examiner notes that Krause teaches that the antibiotic monensin lessened certain negative effects of *P. anaerobius* and *C. sticklandii*, but not *C. aminophilum*. (*Id.*)

The Examiner cites Coleman as disclosing that egg antibodies produced against bacteria, or parts thereof, such as the pilus of *E. coli*, can inhibit the critical disease-causing step of adhesion of the bacteria to the digestive tract of hosts, including food animals. (*Id.* at 7.) The Examiner notes that Coleman describes a number of advantages of egg antibodies, including the fact that "there would be no problem with consumption of milk

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[4] Coleman, U.S. Patent, 5,585,098, issued December 17, 1996.
[5] Pimentel, U.S. Patent 5,741,489, issued April 21, 1998.

from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics." (*Id.*)

The Examiner cites Pimentel as disclosing that "egg antibodies are more resistant to degradation by gastric acidity when they are prepared from whole egg as compared to purified antibodies from the yolk." (*Id.*) The Examiner notes that Pimentel "further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of enterotoxigenic *E. coli* onto enterocytes within the intestinal tract and thereby increasing feed conversion and body weight gain in food animal such as piglets and calves." (*Id.*)

The Examiner concludes that it would have been obvious "to substitute the immunogen *E. coli* as taught by [Tokoro] or [Pimentel] for the immunogens such as *P. anaerobius*, *C. sticklandii,* and *C. aminophilium* [sic] that are responsible for protein wasting in food animal[s] as taught by Krause"; to produce antibody-containing eggs to those organisms by the methods taught in Tokoro, Coleman, and Pimentel; and to feed the antibody-containing compositions to feed animals "to prevent the adherence of *P. anaerobius*, *C. sticklandii*, or *C. aminophilium* [sic] in the intestinal tract of the animal as a method of promoting the growth of food animal." (*Id.* at 7-8.)

As motivation for practicing the claimed process the Examiner cites the teaching in Krause that *P. anaerobius*, *C. sticklandii,* and *C. aminophilum* are responsible for protein waste in food animals, as well as the teachings in Tokoro, Coleman, and Pimentel regarding the advantages of using antibodies from bird eggs to inhibit deleterious microorganisms in the digestive tracts of food animals. (*Id.* at 8.)

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

> When evaluating claims for obviousness, the examiner must consider
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> (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have had a reasonable expectation of success.

In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1443 (Fed. Cir. 1991).

A proper § 103 analysis also requires "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342, 68 USPQ2d 1940, 1947 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974)).

Appellants contend that the Examiner has not established a prima facie case of obviousness. (Br. 10-14.) We agree. In our view, the Examiner has not demonstrated that the references would have suggested inoculating birds with isolated P antigen, as required by claim 14. As discussed *supra*, we interpret claim 14 to require immunization of birds with P antigen that has been isolated from whole cells by, for example, centrifuging cultured cells of *P. anaerobius* and collecting the supernatant.

We agree with the Examiner that, because Krause identifies *P. anaerobius* as causing the waste of dietary protein in food animals, the reference suggests inoculating birds with cells of the organism, so as to produce antibodies to the organism in the birds' eggs. However, we do not see, and the Examiner does not point to, any evidence suggesting that those skilled in the art would have found it obvious to separate the cells of the organism from the culture supernatant, and inoculate birds with the P antigen-containing culture supernatant rather than the cells. Nor has the Examiner shown that the cited references would have provided a reasonable expectation that inoculating birds with the culture supernatant of *P. anaerobius* (or P antigen isolated by any other method) would have yielded antibodies capable of inhibiting the organism in the digestive tracts of food animals.

Thus, in our view, the Examiner has not established that one of ordinary skill would have been motivated to inoculate birds with P antigen from *P. anaerobius*, with a reasonable expectation that doing so would have successfully produced antibody capable of inhibiting *P. anaerobius*.

Because the Examiner has not adequately demonstrated how the references suggest all of the limitations in claim 14, we reverse the obviousness rejection of claim 14.

As discussed *supra*, claims 15 and 16, like claim 14, require the practitioner to inoculate birds with isolated CS or CA antigen (e.g., recovered as a culture supernatant separated from whole cells). The obviousness analysis applied to claim 14 therefore applies equally to claims 15 and 16.

Because the Examiner has not adequately shown how the cited references suggest inoculating birds with isolated CS or CA antigen as recited in claims 15 and 16, respectively, we reverse the obviousness rejection of claims 15 and 16.

3. OBVIOUSNESS OF CLAIMS 19-24 AND 27-32

Claims 19-24 and 27-32 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Tokoro, Krause, Coleman, and Pimentel, as applied to claims 14-16, and further in view of Adalsteinsson[6] and Betz.[7] (Answer 9.)

We reverse this rejection as well. Each of claims 19-24 and 27-32 recites, or depends from a claim that recites, the inoculation of a bird with either P antigen, CS antigen, or CA antigen. As discussed *supra*, the Examiner has not adequately shown where Tokoro, Krause, Coleman, and Pimentel suggest these limitations. We see nothing in Adalsteinsson, Betz, or the Examiner's reasoning that remedies the deficiencies of Tokoro, Krause, Coleman, and Pimentel. We therefore reverse the obviousness rejection of claims 19-24 and 27-32.

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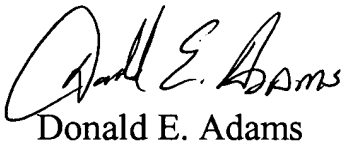
[6] Adalsteinsson et al., U.S. Patent 6,086,878, issued July 11, 2000.
[7] Betz et al., U.S. Patent 4,166,867, issued September 4, 1979.

SUMMARY

Because the Examiner has not established that the cited references suggest all of the limitations in claims 14-16, 19-24, and 27-32, we reverse the obviousness rejections of those claims.

REVERSED



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